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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,046	07/08/2003	Mladen Mercep	03818/100L652-US1	9782
7278	7590	08/10/2004	EXAMINER PESELEV, ELLI	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,046	MERCEP ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-13 and 36-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound wherein M represents a group of Formula II, L represents group of Formula IV, V represents a group of Formula X, NSAIDs, does not reasonably provide enablement for any macrolide, for any non-steroidal anti-inflammatory subunit or any liker molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The terms "macrolide" and "linker molecule" encompass a large number of compounds of diverse structural formulas and it would take an undue amount of experimentation to determine which specific compounds will have a desired activity.

Claims 38-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 38-43 are directed to the treatment of inflammatory diseases with a compound of claim 1. However, note that claim 1 encompasses compound wherein M is a macrolide having antibacterial activity attached to a neoplasitic subunit. There is a good reason to doubt that such a compound would possess anti-inflammatory activity.

Claims 44-48 are directed to the treatment of viral diseases with the compound of claim 1. Claim 45 is directed to the treatment of HIV with a compound of claim 1. However, the compound of claim 1 encompasses a compound wherein M is a macrolide

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having antibacterial activity attached to an anti-inflammatory steroid subunit or to an antioplastic subunit. There is a good reason to doubt that such compounds possess antiviral activity nor there is any evidence of record showing that such compounds possess antiviral activity. Further, there is no evidence that any compounds encompassed by claim 1 possess anti-HIV activity. Due to the high unpredictability of treating HIV, there is a good reason to doubt the effectiveness of the claimed method in the absence of any evidence to support said claim.

Claims 49-51 are directed to the treatment of neoplasia with a compound of claim 1. However, note that claim 1 encompasses compounds wherein M is a macrolide having antibacterial activity attached to an antiviral subunit. There is a good reason to doubt that such a compound would possess antineoplastic activity.

Claims 14-36, 38 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-35 are improper in that a period is missing at the end of said claims.

Claim 36 is indefinite in that variables M, L and V have not been defined.

Regarding claim 38, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 43 is indefinite in that "Formula I" has not been defined.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10/615,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant application are encompassed by the compounds of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of copending Application No. 10/615,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant application are encompassed by the compounds of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Griffin et al by Griffin et al (U.S. Patent No. 6,566,509).

Griffin et al disclose the claimed compound (see, for example, Fig. 31).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the International Patent WO 97/41255.

The International Patent discloses the claimed compound (see, for example, Fig. 7B).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

Elli Peselev
**ELLI PESELEV
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GROUP 1200**